

**Amendment and Response**

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Serial No.: 09/600,432

Confirmation No.: 3387

Filed: October 2, 2000

For: PEPTIDES WITH  $\beta$ 1 INTEGRIN SUBUNIT DEPENDENT CELL ADHESION MODULATING ACTIVITY**Remarks**

The Office Action mailed October 27, 2003 has been received and reviewed. The pending claims are 6-11 and 23-36. Claims 23-28 and 30-36 being withdrawn from examination by the Examiner, claims 6-11 and 29 are currently under examination. Applicants acknowledge, with appreciation, the Examiner's indication that claim 29 is allowed. Claims 6, 30-33, and 35 have been amended. Support for amended claims 6, 30-33 and 35 is found, for example, on page 6, lines 28-29 of the specification. Reconsideration and withdrawal of the rejections are respectfully requested.

**Request for Rejoinder**

Claims 23-28, directed to a process for using a product, were previously withdrawn from examination pursuant an election filed in response to the Restriction Requirement mailed February 19, 2002. Claims 23-28 include all the limitations of examined product claims 6-11. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), withdrawal of the restriction requirement, and rejoinder and examination of the previously withdrawn claims 23-28 is respectfully requested.

Further, Applicants request rejoinder of claims 30-36, drawn to "peptide[s] of no more than about ten amino acid residues" (claim 30), "peptide[s] of no more than about 25 amino acid residues" (claim 31), "peptide[s] of no more than about 50 amino acid residues" (claim 32), "peptide[s] of up to about 100 amino acid residues" (claims 33 and 34), and "peptide[s]" (claims 35 and 36), wherein the peptides have "the sequence Pro-Arg-Ala-Arg-Ile-Tyr (SEQ ID NO:24), Arg-Ala-Arg-Ile-Tyr (SEQ ID NO:25), Ala-Arg-Ile-Tyr (SEQ ID NO:26), or Arg-Ile-Tyr," and wherein the peptides "retain a C-terminal Ile-Tyr dipeptide sequence." Claims 30-36 were newly added with the Applicants' Amendment and Response filed August 6, 2003. As the Office Action mailed October 27, 2003 presents no reason for the withdrawal of claims 30-36, Applicants request clarification. If the withdrawal of claims 30-36 is pursuant to the Restriction Requirement mailed February 19, 2002 and Applicants' Election filed March 13, 2002 (electing Group I, drawn to

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peptides consisting of six amino acids), Applicants request reconsideration and withdrawal of the restriction requirement and rejoinder of claims 30-36.

It is respectfully submitted that the examination of claims 30-36 does not place an undue burden on the Examiner. This is particularly true in view of the Examiner's citation of Newsholme et al. (*Journal of Biological Chemistry* 267(2), 810-818, 1992), Ohba (U.S. Patent No. 5,359,048), and Westerlink (*Proc Natl Acad Sci* 92, 4-21, 1995) to substantiate rejections under 35 U.S.C. §102(b) in the Office Action mailed May 8, 2003. In the Office Action mailed May 8, 2003, Newsholme et al. is cited for teaching a peptide that is twenty-five amino acids in length (fourth from last peptide shown in Table 1, page 811 of Newsholme et al.), Ohba et al. is cited for teaching a peptide that is 1149 amino acids in length (spanning columns 17-261 of Ohba et al.), and Westerlink et al. is cited for teaching a peptide that is thirteen amino acids in length (peptide 3 shown in Table 1, p. 4023 of Westerlink et al.). Thus, Applicants' respectfully submit that the Examiner has already searched and examined peptides longer than six amino acids residues in length and the examination of claims 30-36 does not place an undue burden on the Examiner. Rejoinder of claims 30-36 is respectfully requested.

**The 35 U.S.C. §102 Rejection**

The Examiner rejected claims 6-11 under 35 U.S.C. §102(b) as being anticipated by Carraway et al. (*Peptides* (New York, NY, United States) 14(1), 37-45, 1993), and by Qi et al. (*Shengwu Huaxue Zazhi* 13(5), 576-579, 1997). This rejection under 35 U.S.C. §102(b) is respectfully traversed.

As amended, claims 6-11 are drawn to peptides, "wherein said peptide retains a C-terminal Ile-Tyr dipeptide sequence." As asserted by the Examiner, Carraway et al. teaches the peptide Arg-Arg-Ile-Tyr-Ile-Leu (page 2, Office Action mailed October 27, 2003) and Qi et al. teaches the peptide Ac-Cys-Pro-Arg-Ile-Tyr-Asn-NH<sub>2</sub> (page 3, Office Action mailed October 27, 2003). It is respectfully submitted that neither the peptide taught by Carraway et al. nor the peptide taught by Qi et al. "retains a C-terminal Ile-Tyr dipeptide sequence." Thus, the disclosures of Carraway et al. and

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Qi et al. do not set forth each and every element of claims 6-11. Withdrawal of this rejection under 35 U.S.C. §102(b) is respectfully requested.

In addition, the peptides of dependant claims 7-11 and withdrawn claims 31-36 include various functional limitations. The peptide of claims 7, 31, 32, 33, and 35 "modulates  $\beta$ 1 integrin subunit dependent adhesion," the peptide of claim 8 "inhibits  $\beta$ 1 integrin subunit dependent adhesion," the peptide of claim 9 "modulates  $\alpha$ 4 $\beta$ 1 integrin dependent adhesion," the peptide of claim 10 "inhibits  $\alpha$ 4 $\beta$ 1 integrin dependent cell adhesion," and the peptide of claims 11, 34 and 36 "inhibits  $\alpha$ 4 $\beta$ 1 integrin dependent adhesion of Ramos cells to  $\alpha$ 4 $\beta$ 1 integrin binding fibronectin fragments."

Applicants respectfully submit that none of these functional limitations are taught by Carraway et al. or Qi et al. Indeed, in rejecting claims 7-11, the Examiner acknowledged this, stating that Carraway et al. and Qi et al. make "no mention of  $\beta$ 1 integrin or  $\alpha$ 4 $\beta$ 1 integrin" (page 3, Office Action mailed October 27, 2003). However, the Examiner asserted that "as asserted in the specification, any peptide which contains the tripeptide Arg-Ile-Tyr exhibits [the claimed] propert[ies]. Thus, the claims are anticipated" (page 3, Office Action mailed October 27, 2003). Applicants adamantly disagree. The Examiner is invited to substantiate his assertions. Rather, Applicants respectfully submit that the specification teaches that it is peptides that retain the C-terminal Ile-Tyr dipeptide sequence that are capable of inhibiting  $\beta$ 1 integrin dependent cell adhesion (see, for example, page 6, lines 28-30 of the specification). Applicants submit that neither Carraway et al. nor Qi et al. disclose peptides with the claimed functional properties of claims 7-11.

In view of the above discussion, withdrawal of the rejection of claims 6-11 under 35 U.S.C. §102(b) is respectfully requested.

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It is respectfully submitted that the pending claims 6-11 and 23-36 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for

**MCCARTHY et al.**

By

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 27 day of January, 2003, at 1:30 pm (Central Time).

By:

Name:

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